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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,449	12/13/2005	James Edward Eyles	41577/317929	5114
23370 7590 04/02/2007 JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			EXAMINER SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/02/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/542,449

Applicant(s)

EYLES ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17 is/are rejected.
- 7) ☒ Claim(s) 2 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicants' Preliminary Amendment, received 15 July 2005, is acknowledged. Claims 2-15; 17 have been amended. Claim 16 has been cancelled.
2. Claims 1-15 and 17 are pending and under consideration.

### Specification

3. The disclosure is objected to because of the following informalities:

Page 1, line 11, "utilise" should be "utilize".

Page 3, line 17, "region" should be "regions"; line 20 "nucleic acids" should be "amino acids".

Page 4, line 2, "aerosolised" should be "aerosolized"; line 34, "biodegradable" should be "biodegradable".

Page 5, line 6, "stabilise" should be "stabilize"; line 11, "the a" should be "that a".

Page 6, lines 2 and 6, "lyophilisation" should be "lyophilization".

Page 7, line 8, delete the period following *Yersinia*; line 9, " aerosolised" should be "aerosolized"; line 11, "immunisation" should be "immunization".

Page 8, line 11, insert the heading "Brief Description of the Drawings"; line 15, "titre" should be "titer"; lines 16, 20, 24, and 28, "aerosolised" should be "aerosolized".

Page 9, lines 11, 17, and 20, "aerosolised" should be "aerosolized"; line 12, "analyse" should be "analyze"; lines 14 and 24, "analysed" should be "analyzed"; line 23, clarify "The was repeated"; line 32, "aerosolisation" should be "aerosolization".

Page 10, lines 2, 16, and 17, "aerosolised" should be "aerosolized"; line 4, "immunising" should be "immunizing"; line 5, "titres" should be "titers"; line 11, "aerosolisation"

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should be "aerosolization"; line 24, "visualisation" should be "visualization"; line 29, clarify "can reach enter".

Appropriate correction is required.

### **Drawings**

4. Figure 2 is objected to because "TITRE" should be "TITER".
5. Figure 3 is objected to because "immunised" should be "immunized".
6. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### **Claim Objections**

7. Claim 2 is objected to because of the following informality: line 2, "sequences" should be "sequence". Appropriate correction is required.

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8. Claim 10 is objected to because of the following informality: line 2, "lyophilised" should be "lyophilized". Appropriate correction is required.

**Claim Rejections - 35 USC § 112**

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, because the claim recites the limitation "free reagent to the reagent associated with the microspheres" in line 2. There is insufficient antecedent basis for this limitation in the claim because claim 12 recites "free form", not "free reagent", and claim 11 does not recite reagent "associated with the microspheres", but "encapsulated within the microspheres".

11. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is the metes and bounds of reagent "associated" with the microspheres. The specification does not define such an "association".

**Claim Rejections - 35 USC § 102**

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Eyles et al (*Vaccine*, 19:4732-4742, 2001).

The claims are drawn to a formulation comprising biodegradable microspheres of average diameter 0.5—5  $\mu\text{m}$  comprising a nonliving reagent which produces a protective immune response in a mammal.

Eyles et al teach a formulation comprising biodegradable microspheres of 1.5  $\mu\text{m}$  average diameter comprising *Y. pestis* V antigen (abstract; Methods and Materials, pages 4733-34).

#### **Claim Rejections - 35 USC § 103**

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eyles et al (*Vaccine*, 19:4732-4742, 2001) in view of Britto et al (U.S. Pat. No. 6,098,619, 8Aug2000).

The claim is drawn to a formulation comprising biodegradable microspheres of average diameter 0.5—5  $\mu\text{m}$  comprising a nonliving reagent which produces a protective immune response in a mammal. The formulation is contained within a nebulizer or inhaler.

Eyles et al teach a formulation comprising biodegradable microspheres of 1.5  $\mu\text{m}$  average diameter comprising *Y. pestis* V antigen (abstract; Methods and Materials, pages 4733-34). Eyles et al do not teach the formulation contained within a nebulizer or inhaler.

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Britto et al teach an inhaler apparatus for delivery of medicaments to the lungs of a subject (Abstract; claims 1-11).

Thus, it would have been obvious to one skilled in the art of medicament delivery to utilize the inhaler systems of Britto et al to deliver the formulations of Eyles et al in order to provide the most efficacious use of the formulations of Eyles et al.

### **Conclusion**

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 30, 2007

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER